

2. Written Description Requirement Rejection

A. **Current Rejection**

Examiner has rejected claims 3-6 and 16-22 under 35 U.S.C. 112, first paragraph, as allegedly “containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art...” Office Action ¶ 2. In support of the rejection Examiner asserts that “Considering claims 3-6 and 11-22,¹ no support is found for the claim combinations.” Id.

B. **Response**

Applicant respectfully requests clarification of this rejection, or in the alternative and for the reasons stated below, that the rejection be withdrawn. As provided in the MPEP § 2163.04, the Examiner has the burden of explaining, in detail, why the claims do not meet the written description requirement:

The examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. 541 F.2d at 265, 191 USPQ at 98. (other citations omitted).

Any time an examiner bases a rejection of a claim ..., the examiner should (A) identify the claim limitation not described; and (B) provide reasons why persons skilled in the art at the time the application was filed would not have recognized the description of this limitation in the disclosure of the application as filed. A typical reason points out the differences between what is disclosed and what is claimed.

MPEP § 2163.04. Applicant respectfully submits that the Examiner has not provided sufficient reasons for the rejection such that Applicant may respond.

Further, Applicant would like to bring to Examiner's attention the fact that this same rejection was previously made, and in view of a detailed response, the Examiner withdrew this rejection. In particular, claims 3-6 and 16-22 were rejected under 35 U.S.C. § 112, first paragraph, allegedly for lack of written description. (See Office Action dated 9/30/98, at ¶ 4). Applicant submitted a detailed response which addressed the issues raised in the rejection (See Second Amendment dated 12/30/98). Subsequently, in light of the amendments

¹ Though the Examiner identified claims 11-22, it is presumed that Examiner meant to indicate claims 16-22.

and responsive remarks, Examiner Luther withdrew the 112 rejection. (See Office Action dated 3/17/99 (asserting only a 103 rejection)). **Accordingly, for the same reasons submitted by Applicant in its Second Amendment (dated 12/30/98), applicant requests that Examiner withdraw this 112 rejection.**

3. Enablement Requirement Rejection

A. Current Rejection

Examiner has rejected claims 3-6 and 11-12² under 35 U.S.C. 112, first paragraph, as allegedly “containing subject matter which was not described in the specification in such a way as to reasonably convey to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.” Office Action ¶ 3. In support of the rejection Examiner asserts that “Considering claims 3-6 and 11-22³, it would appear that the ordinary artisan of 7/2/96 would have required undue experimentation for making and using the claimed invention. An explanation is required for demonstrating otherwise (supported by evidence when appropriate). See MPEP 2163+.” Id.

B. Response

Applicant respectfully requests clarification of this rejection, or in the alternative and for the reasons stated below, that the rejection be withdrawn. As provided in the MPEP § 2164.04, the Examiner has the burden of explaining, in detail, reasons why there is uncertainty as to enablement:

In order to make [an enablement] rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35

² Though the Examiner identified claims 11-12, it is presumed that Examiner meant to indicate claims 16-22.

³ Though the Examiner identified claims 11-22, it is presumed that Examiner meant to indicate claims 16-22.

U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis. In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." 439 F.2d at 224, 169 USPQ at 370.

According to In re Bowen, 492 F.2d 859, 862-63, 181 USPQ 48, 51 (CCPA 1974), the minimal requirement is for the examiner to give reasons for the uncertainty of the enablement. This standard is applicable even when there is no evidence in the record of operability without undue experimentation beyond the disclosed embodiments. See also In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (citing In re Bundy, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981)) (discussed in MPEP Section 2164.07 regarding the relationship of the enablement requirement to the utility requirement of 35 U.S.C. 101).

While the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP Section 2164.01(a)(a) and the evidence as a whole, it is not necessary to discuss each factor in the written enablement rejection.⁴ The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact. For example, doubt may arise about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation. In such a case, the examiner should specifically identify what information is missing and why one skilled in the art could not supply the information without undue experimentation. See MPEP Section 2164.06(a)(a). References should be supplied if possible to support a prima facie case of lack of enablement, but are not always required. In re Marzocchi, 439 F.2d 220, 224, 169

⁴ These factors include, but are not limited to: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement)

USPQ 367, 370 (CCPA 1971). **However, specific technical reasons are always required.**

MPEP § 2164.04 (footnote added) (bolded emphasis added). Applicant respectfully submits that the Examiner has not provided sufficient detail to which Applicant may respond.

Further, Applicant would like to bring to Examiner's attention the fact that this same rejection was previously made, and in view of a detailed response, the Examiner withdrew this rejection. In particular, claims 5 and 6 were rejected under 35 U.S.C. § 112, first paragraph allegedly for lack of enablement. (See Office Action dated 04/09/98, at ¶ 12). Applicant submitted a detailed response which addressed the issues raised in the rejection (See Amendment dated 07/02/98). Subsequently, in light of the amendments and responsive remarks, Examiner Kizou withdrew the 112 rejection. (See Office Action dated 09/30/98 (asserting a different 112 rejection and a 102 rejection, but not asserting the non-enablement rejection)). **Accordingly, for the same reasons submitted by Applicant in its Amendment (dated 07/02/98), applicant requests that Examiner withdraw this 112 rejection.**

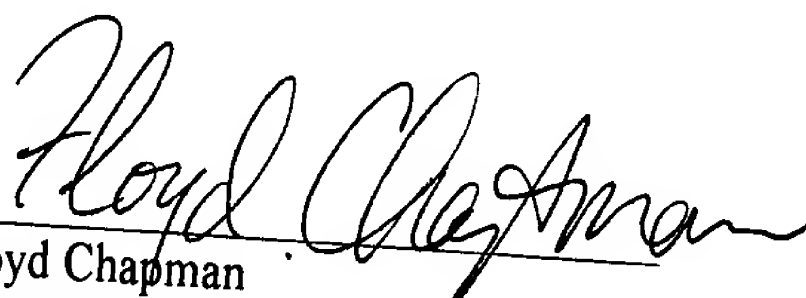
CONCLUSION

Applicant maintains that this application is in condition for allowance, and such disposition is earnestly solicited. If the Examiner believes that an interview with Applicant's representative, either by telephone or in person, would further prosecution of this application, we would welcome the opportunity for such an interview.

Respectfully submitted,

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